

## REMARKS

In this response to the Office Action dated February 4, 2010, Claims 1 and 18 have been amended. Support for these amendments can be found, for example, from page 13, lines 14-15 of the specification as originally filed. No new matter has been added in these amendments. Claims 1, 4, 8-12, and 15-18 are currently pending.

### **Rejections under 35 U.S.C. § 103**

Claims 1, 4, 8-12, and 15-18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kodama *et al.* (WO 97/02821 A2) and Itoh *et al.* (U.S. Patent No. 5,466,820 A).

Claims 1, 4, 8-12, and 15-18 as amended in this response recite, among others, the content of water-soluble plasticizer to 1 to 10 folds with respect to the content of the film-forming agent. This technical feature is important to an activity of an antifungal medicinal composition or a method of producing the composition in the presently claimed invention.

For example, the foregoing feature contributes to the formation of the antifungal medicinal composition in a form of a coating film, which has a plastic property when applied to an application target. This coating film would be in a viscous glass state. (*See*, for example, page 18, lines 12-15 of the originally filed specification) The film with such viscosity would be present on the skin as a gel-like substance, not a sheet-like thin film. Prior to the present application, antifungal agents were generally formulated to form a sheet-like thin film when applied to skin. Such agents in a sheet-like thin film form typically contained approximately 10%-30% of water-soluble plasticizer with respect to film-forming agent in which the amount of the plasticizer is significantly less than that in the present invention.

The viscous glass state of the film allows the easy and efficient movement of a drug from the coating film to the affected area. As a result, the drug can be supplied to the affected area at a predetermined concentration; in other words, the drug availability would be substantially increased in the claimed composition. Accordingly, the antifungal medicinal composition of the present invention can be effectively used, for example, as an external application for the treatment of fungal diseases in the excessive keratinized portion of the skin and the thickened portion of the skin around the foot where the administration effect of the general antifungal medicinal composition for external application is hardly obtained. Consequently, the antifungal medicinal composition of the present invention can be used to the affected area of the excessive keratinized

portion of the nail or skin, or the thickened skin portion around the foot with high efficiency. (See, for example, page 19, line 11-page 20, line 2 of the specification)

The Examiner asserted that Itoh would teach an antifungal agent comprising ethyl cellulose, hydroxypropylmethylcellulose phthalate, Pluronic F68, and Eudragit (column 12, Lines 38-45 of Itoh). In view of Pluronic F68 and Eudragit being a respective example of a film-forming agent and a plasticizer in the present application, the Examiner appears to understand that Itoh would teach an antifungal agent comprising a film-forming agent and a water-soluble plasticizer. Itoh reference, however, is completely silent in teaching or suggesting any ratio between the film-forming agent and the plasticizer and moreover any benefits obtained with such technical feature. As such, Itoh clearly fails to teach or suggest all the features of the pending claims. Furthermore, Kodama fails to teach or suggest any ratio between a film-forming agent and a plasticizer. As such, it would be highly unlikely for a skilled artisan to produce the claimed antifungal composition comprising the film-forming agent and the water-soluble plasticizer with the specific ratio as recited in the pending claims in light of the prior art. Accordingly, the subject matter of the pending claims is not and cannot be obvious over Kodama and Itoh. Applicants respectfully request withdrawal of the rejection and reconsideration of Claims 1, 4, 8-12, and 15-18.

#### **No Disclaimers or Disavowals**

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

**Application No.:** 10/518,776  
**Filing Date:** December 17, 2004

### **CONCLUSION**

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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